May 12, 2022

Veru Reports Second Quarter Fiscal 2022 Results and Progress of Sabizabulin for COVID-19 Toward a Request for Emergency Use Authorization

--FDA States that Veru Should Submit Request for Emergency Use Authorization (EUA) Application Based on Positive Efficacy and Safety Data from the Phase 3 Clinical Study of Sabizabulin in Hospitalized COVID-19 Patients--

--IDMC Unanimously Votes to Halt the Ongoing Phase 3 Trial of Sabizabulin for Hospitalized COVID-19 Patients at High Risk of ARDS Due to Overwhelming Efficacy and Safety with 55.2% Reduction in Death--

--EUA Application Submission for Sabizabulin COVID-19 Treatment Expected by Calendar Q2 2022--

-- Phase 3 ENABLAR-2 Clinical Trial of Enobosarm and Abemaciclib Combination Therapy in Metastatic Breast Cancer is Enrolling --

-- Company to Host Investor Conference Call Today at 8 AM ET--

MIAMI, May 12, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and ARDS-related diseases and for the management of breast and prostate cancers, today announced financial results for its fiscal 2022 second quarter ended March 31, 2022.

Second Quarter Financial Summary: Fiscal 2022 vs Fiscal 2021

- Total net revenues decreased 2% to $13.0 million from $13.3 million
- US FC2 prescription net revenues climbed 12% to $11.6 million from $10.3 million
- Gross profit rose 2% to $11.2 million from $10.9 million
- Gross margin increased to 86% of net revenues from 82% of net revenues, a record high compared to any prior quarter
- Operating loss was $11.8 million versus $1.5 million
- Net loss was $14.2 million, or $0.18 per share, compared $2.8 million, or $0.04 per share

Year-to-Date Financial Summary: Fiscal 2022 vs Fiscal 2021

- Total net revenues decreased 3% to $27.2 million from $28.0 million
- US FC2 prescription net revenues climbed 19% to $23.2 million from $19.4 million
- Gross profit rose 6% to $23.0 million from $21.7 million
- Gross margin increased to 85% of net revenues from 78% of net revenues
- Operating loss was $16.7 million compared with operating income of $17.7 million, which included an $18.4 million gain on the December 2020 sale of the PREBOOST® business
- Net loss was $20.6 million or $0.26 per diluted share compared with net income, which included the gain on the sale of the PREBOOST business, of $14.4 million or $0.18 per diluted share

Balance Sheet Information

- Cash and cash equivalents were $112.0 million as of March 31, 2022 versus $122.4 million at September 30, 2021
- Net accounts receivable of $8.1 million as of March 31, 2022 versus $8.8 million as of September 30, 2021

“Following a positive Phase 3 COVID-19 clinical study where sabizabulin treatment resulted in a clear clinical benefit by significantly reducing deaths, we met with FDA for a Pre-EUA meeting on May 10, 2022. FDA agreed that our development program had sufficient efficacy and safety data to support a request for EUA application. No additional efficacy or safety studies will be required,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “The Agency has been incredibly responsive, and we look forward to submitting a request for Emergency Use Authorization application as soon as possible. The high mortality rates observed in hospitalized moderate to severe COVID-19 patients in the placebo group underscores that this remains a high unmet medical need. We look forward to updating you as we advance sabizabulin to these high-risk patients.”

Dr. Steiner added: “We continue to make great progress on our clinical programs for breast and prostate cancer. We now have 2 enrolling Phase 3 metastatic breast cancer clinical trials and one Phase 3 prostate cancer clinical trial. The Phase 3 COVID-19 clinical study is completed and met its primary endpoint. In our commercial business, we continue to see an increase in FC2 prescriptions and plan to launch ENTADFI soon. We also expect to have significant near-term revenue from sabizabulin for the treatment of hospitalized COVID-19 patients at high risk for ARDS, if EUA is granted by U.S. FDA.”

Pharmaceutical Pipeline Highlights:

COVID-19 Program; Other Viral and ARDS-Related and Inflammatory-Related Diseases

Sabizabulin for the Treatment of Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS) Phase 3 COVID-19 Clinical Study – Study Unanimously Halted by the Independent Data Monitoring Committee (IDMC) After a Planned Interim Analysis for Overwhelming Efficacy; Company Preparing an EUA Submission.

A randomized, double-blind, placebo-controlled global Phase 3 clinical trial was conducted in hospitalized patients with moderate to severe COVID-19 infection who were at high risk for

ARDS and death. Patients were randomly assigned to receive sabizabulin 9mg or placebo once oral daily for up to 21 days in a 2:1 ratio. The primary endpoint was all-cause mortality up to day 60, and key secondary endpoints were days in intensive care unit (ICU), days on mechanical ventilation, and days in hospital.

A total of 204 patients underwent randomization (with 134 assigned to sabizabulin-treated group and 70 assigned to placebo-treated group). Both groups were allowed to receive standard of care. Baseline characteristics were similar in the two groups. The superiority of sabizabulin was demonstrated at the planned interim analysis conducted in the first 150 patients randomized into the study with 98 patients receiving sabizabulin and 52 patients received placebo. The IDMC unanimously voted to halt the Phase 3 because of overwhelming efficacy. Sabizabulin treatment resulted in a clinically meaningful and statistically significant 55.2% relative reduction in deaths compared to placebo in hospitalized patients with moderate to severe COVID-19 infection who were at high risk for ARDS and death with a lower incidence of adverse events and serious adverse events compared to placebo.

FDA agreed that the Phase 3 COVID-19 study is sufficient to support the efficacy portion of a request for EUA submission and for an NDA submission.

FDA also agreed that the current safety data available for sabizabulin is sufficient to support the safety portion of a request for EUA submission. FDA informed the Company that additional safety data that would be collected during the use of sabizabulin under the EUA, if granted, will be sufficient to support an NDA submission, and furthermore, that no additional safety clinical studies are required.

The Company plans to submit a request for an EUA application in calendar 2Q 2022.

The Company has scaled up manufacturing processes and will be able to produce commercial drug supply to address anticipated drug needs following potential FDA authorization and subsequent authorizations in the U.S. as well as other countries and regions.

The Company has initiated discussions with government agencies to discuss government purchases of sabizabulin in the U.S. and other countries around the world.

Breast Cancer Program

Enobosarm, a Novel Oral Selective Androgen Receptor Targeting Agonist, for the 3rd Line Treatment of AR+ ER+ HER2- Metastatic Breast Cancer with AR ≥ 40% Expression - Phase 3 ARTEST Clinical Study- Enrolling.

Enobosarm is an oral, new chemical entity, selective androgen receptor targeting agonist that activates the androgen receptor (AR), a tumor suppressor, in AR+ER+HER2- metastatic breast cancer without causing unwanted masculinizing side effects. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in approximately 1,450 subjects dosed, including three Phase 2 clinical studies in advanced metastatic breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+ER+HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that

previously failed estrogen receptor blocking agents, chemotherapy, and/or CDK 4/6 inhibitors and enobosarm was well tolerated with a favorable safety profile.

We are enrolling the Phase 3 multicenter, international, open label, and randomized (1:1) ARTEST registration clinical trial design to evaluate enobosarm monotherapy versus physician's choice of either exemestane everolimus or a selective estrogen receptor modulator (SERM) as the active comparator for the treatment of AR+ ER+ HER2- metastatic breast cancer in approximately 210 patients with AR expression ≥40% in their breast cancer tissue who had previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. In January 2022, the FDA granted Fast Track designation to the ARTEST Phase 3 registration program, a distinction that underscores the urgent need for novel, targeted therapies for this important unmet medical need.

Enobosarm and Abemaciclib, CDK 4/6 Inhibitor, Combination Therapy for the 2nd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with AR ≥ 40% Expression- Phase 3 ENABLAR-2 Clinical Study-Enrolling.

We are enrolling the Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the treatment of the enobosarm and abemaciclib combination versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed first line palbociclib (a CDK 4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and who have an AR ≥ 40% expression in their breast cancer tissue in approximately 186 subjects. We have a clinical trial collaboration and supply agreement with Lilly for our Phase 3 ENABLAR-2 trial.

Sabizabulin, Novel Oral Cytoskeleton Disruptor Agent, for the 3rd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with AR< 40% Expression- Phase 2b Clinical Study.

We intend to conduct a Phase 2b clinical study which will be an open label, multicenter, and randomized (1:1) study evaluating sabizabulin 32mg monotherapy versus active comparator (exemestane ± everolimus or a SERM, physician's choice) for the treatment of AR+ ER+ HER2- metastatic breast cancer in approximately 200 patients with AR <40% expression in their breast cancer tissue who have previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

Prostate Cancer Program

Sabizabulin for the Treatment of Metastatic Castration and Androgen Receptor Targeting Agent Resistant Prostate Cancer – Phase 3 VERACITY Clinical Study - Enrolling.

The Company is enrolling the open label, randomized (2:1), multicenter Phase 3 VERACITY clinical study evaluating sabizabulin 32mg versus an alternative androgen receptor targeting agent for the treatment of chemotherapy naïve men with metastatic castration resistant prostate cancer who have tumor progression after previously receiving at least one androgen receptor targeting agent. The primary endpoint is radiographic progression free survival in approximately 245 patients from 45 clinical centers.

VERU-100, a Novel Proprietary Long-Acting Gonadotropin-Releasing Hormone (GnRH) Antagonist Peptide 3-Month Subcutaneous Depot Formulation, for Androgen Deprivation Therapy of Advanced Prostate Cancer – Phase 2 Clinical Study - Enrolling.

VERU-100 is designed to address the current limitations of commercially available androgen deprivation therapy. Androgen deprivation therapy is currently the mainstay of advanced prostate cancer treatment and is used as a foundation of treatment throughout the course of the disease even as other endocrine, chemotherapy, or radiation treatments are added or stopped. Specifically, VERU-100 is a chronic, long-acting GnRH antagonist peptide administered as a small volume, three-month depot subcutaneous injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a problem that occurs with currently approved luteinizing hormone-releasing hormone agonists used for androgen deprivation therapy. There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month injection. In June 2021, the Company initiated the Phase 2 dose finding clinical study of VERU-100 androgen deprivation therapy for hormone sensitive advanced prostate cancer. The Phase 2 VERU-100 clinical study is expected to enroll approximately 45 patients. A Phase 3 registration clinical study has been agreed upon with FDA and will enroll approximately 100 men.

Urev - Sexual Health Division

ENTADFI™ (tadalafil and finasteride) capsule, a new Treatment for Benign Prostatic Hyperplasia (BPH) – Received FDA Approval.

We plan to market ENTADFI™ to healthcare providers and patients via digital tactics and distribution that will be conducted through the traditional pharmaceutical distribution channels, and potentially, a third-party telemedicine portal. We will augment our marketing and sales efforts by seeking partners in the U.S. and ex-U.S.

FC2 Female Condom/Internal Condom®

The Company markets and sells the FC2®, an FDA-approved product for dual protection against unplanned pregnancy and the transmission of sexually transmitted infections.

Event Details
Interested parties may access the call by dialing 1-800-341-1602 from the U.S. or 1-412-902-6706 from outside the U.S. and asking to be joined into the Veru Inc. call. The call will also be available through a live, listen-only audio broadcast via the Internet at www.verupharma.com. Listeners are encouraged to visit the website at least 10 minutes prior to the start of the scheduled presentation to register, download and install any necessary software. A playback of the call will be archived and accessible on the same website for at least three months. A telephonic replay of the conference call will be available, beginning the same day at approximately 12 p.m. (noon) ET by dialing 1-877-344-7529 for U.S. callers, or 1-412-317-0088 from outside the U.S., passcode 8215063, for one week.

About Veru Inc.
Veru is a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and ARDS-related diseases and for the management of breast and prostate

cancers. Veru also has a commercial sexual health division - Urev, the proceeds of which help fund its drug development programs, comprised of 2 FDA approved products - ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, for which commercialization launch plans are underway, and FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections which is sold in the U.S. and globally.

Forward-Looking Statements

The statements in this release that are not historical facts are “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding: whether and when the Company will submit an EUA application, or receive an emergency use authorization or any approval from FDA or from any regulatory authority outside the U.S. for sabizabulin for certain COVID-19 patients; whether and when sabizabulin will become an available treatment option for certain COVID-19 patients in the U.S. or anywhere outside the U.S.; whether the Company will have sufficient supply of sabizabulin to meet demand, if an emergency use authorization or other approval is granted; whether the Company will secure any advance purchase agreement with the U.S. government or any foreign government; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company’s drug candidates and companion diagnostic; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope of clinical studies and FDA acceptance of such design and scope; whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company’s drug candidates are or continue to be available; whether the expected commencement and timing of the Company’s clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the U.S. or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company’s development pipeline, and the timing of the Company’s submissions to FDA and FDA’s review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; and whether and when ENTADFI will be commercialized successfully. These forward-looking statements are based on the Company’s current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company’s product portfolio and the results of clinical studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA or other regulatory authorities and any determinations made by the FDA or any other regulatory authority, including the risk that the Company may

not be able to obtain an EUA from the FDA or similar authorizations from other regulatory authorities on a timely basis or at all; any agreements or positions taken by the FDA in a pre-EUA meeting does not bind the FDA or prevent it from later taking a different position, asking for more data or delaying or denying the application; the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company lacks experience in scaling up or commercializing a drug product and may not be able to successfully commercialize sabizabulin as a COVID-19 treatment; the Company may be unable to manufacture sabizabulin as a COVID-19 treatment in sufficient quantities or at sufficient yields; the Company's existing products and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical studies, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to successfully commercialize any of its products, if approved; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; the Company's ability to protect and enforce its intellectual property; the potential that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; the concentration of accounts receivable with our largest customers and the collection of those receivables; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's and third party facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; costs and other effects of litigation, including product liability claims; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the fiscal year ended September 30, 2021 and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. The Company disclaims any intent or obligation to update these forward-looking statements.

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FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2022	September 30, 2021
Cash and cash equivalents	$ 112,015,505	$ 122,359,535
Accounts receivable, net	8,134,690	8,794,224
Inventory, net	6,415,463	5,574,253
Prepaid expenses and other current assets	13,895,695	15,025,475
Total current assets	140,461,353	151,753,487
Plant and equipment, net	1,025,463	592,603
Operating lease right-of-use assets	5,132,655	969,839
Deferred income taxes	13,019,385	13,024,550
Intangible assets, net	4,013,095	4,048,810
Goodwill	6,878,932	6,878,932
Other assets	2,294,366	878,502
Total assets	$ 172,825,249	$ 178,146,723
Accounts payable	$ 7,518,071	$ 3,409,771
Accrued expenses and other current liabilities	9,830,225	9,120,328
Residual royalty agreement liability, short-term portion	3,833,162	3,237,211
Total current liabilities	21,181,458	15,767,310
Residual royalty agreement liability, long-term portion	11,121,490	9,397,136
Operating lease liability, long-term portion	4,445,432	609,921
Other liabilities	78,426	78,412
Total liabilities	36,826,806	25,852,779
Total stockholders' equity	135,998,443	152,293,944
Total liabilities and stockholders' equity	$ 172,825,249	$ 178,146,723

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2022	**2021**	**2022**	**2021**
Net revenues	$ 13,028,394	$ 13,340,487	$ 27,163,526	$ 27,957,476
Cost of sales	1,853,116	2,432,187	4,146,166	6,212,543
Gross profit	11,175,278	10,908,300	23,017,360	21,744,933
Operating expenses:				
Research and development	15,541,104	7,572,813	25,622,265	13,250,567
Selling, general and administrative	7,399,138	4,806,897	14,122,344	9,188,777
Total operating expenses	22,940,242	12,379,710	39,744,609	22,439,344
Gain on sale of PREBOOST®	—	—	—	18,410,158
Operating (loss) income	(11,764,964)	(1,471,410)	(16,727,249)	17,715,747
Non-operating expenses	(2,440,316)	(1,352,881)	(3,743,382)	(3,234,035)
(Loss) income before income taxes	(14,205,280)	(2,824,291)	(20,470,631)	14,481,712
Income tax (benefit) expense	(27,450)	21,690	87,205	99,992
Net (loss) income	$ (14,177,830)	$ (2,845,981)	$ (20,557,836)	$ 14,381,720
Net (loss) income per basic common share outstanding	$ (0.18)	$ (0.04)	$ (0.26)	$ 0.20
Basic weighted average common shares outstanding	80,052,504	75,175,077	80,037,675	72,717,621
Net (loss) income per diluted common share outstanding	$ (0.18)	$ (0.04)	$ (0.26)	$ 0.18

Diluted weighted average common shares outstanding	80,052,504	75,175,077	80,037,675	80,654,070

Veru Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Six Months Ended March 31,	
	2022	**2021**
Net (loss) income	$ (20,557,836)	$ 14,381,720
Adjustments to reconcile net (loss) income to net cash used in operating activities	6,659,447	(15,606,848)
Changes in operating assets and liabilities	1,293,920	(705,137)
Net cash used in operating activities	(12,604,469)	(1,930,265)
Net cash provided by investing activities	2,012,566	14,987,882
Net cash provided by financing activities	247,873	110,028,758
Net (decrease) increase in cash	(10,344,030)	123,086,375
Cash at beginning of period	122,359,535	13,588,778
Cash at end of period	$ 112,015,505	$ 136,675,153

Source: Veru Inc.